IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

FREDERICK DELANO and FRANCES DELANO, Plaintiffs,	)	
vs.	)	Case No. 2:11-cv-02475-SHM-cgc JURY TRIAL DEMANDED
ABBOTT LABORATORIES, Defendant.	)	

MEMORANDUM IN SUPPORT OF
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Defendant Abbott Laboratories ("Abbott") moves, pursuant to Federal Rule of Civil Procedure 56, for summary judgment against Plaintiffs on the grounds that this suit is barred by the applicable Tennessee statute of limitations. Plaintiffs failed to file their suit within one year of discovering their alleged injuries and may not now bring suit more than two and a half years later.

STATEMENT OF FACTS

A. Plaintiffs' Complaint Centers On The Alleged Failure To Adequately Warn Of The Risks of Histoplasmosis Associated With Humira.

Plaintiffs Frederick and Frances Delano filed this personal injury products liability action on June 12, 2011. (Statement of Undisputed Facts, ¶ 1) Plaintiffs allege that Abbott failed to provide adequate warnings of the risks of the prescription drug, Humira, which Mr. Delano received to treat his psoriatic arthritis. (*Id.* ¶¶ 6, 11-13) Humira (generic name is adalimumab), was first approved by the FDA in 2002 for treatment of moderately-to-severely active rheumatoid arthritis and has since been approved in 83 countries for six different conditions. (*Id.*

¶ 2-3) Humira is in a class of biologic drugs called TNF-alpha blockers. (*Id.* ¶ 4) Humira was approved by the FDA for treatment of psoriatic arthritis in January 2008. (*Id.* ¶ 5)

In October 2008, Mr. Delano's physicians prescribed Humira to treat his psoriatic arthritis, and he received Humira treatments approximately every two weeks for the next two and a half months. (*Id.* ¶ 6) In December 2008, Mr. Delano began experiencing flu-like symptoms and discontinued use of Humira in approximately mid-December 2008. (*Id.* ¶¶ 6-7) In early February 2009, he was admitted to the VA hospital, underwent tests, and later was admitted to Saint Francis Hospital. (*Id.* ¶ 8) Physicians there diagnosed him with histoplasmosis, an infection caused by the histoplasma fungus, which is endemic to the Mississippi Valley region in which Memphis sits. (*Id.* ¶¶ 8-10) In the Mississippi Valley, 80-90% of the public is exposed to the histoplasma fungus. (*Id.* ¶ 10)

Although the Humira label in effect at the time Mr. Delano received Humira expressly warned of the risk of histoplasmosis, (*Id.* ¶¶ 14-18), plaintiffs claim that this warning was not strong enough. (*Id.* ¶¶ 11-12) Plaintiff's allege three counts against Abbott arising from Mr. Delano's use of Humira: (1) strict liability violations of the Tennessee Products Liability Act; (2) negligence; and (3) breach of warranty. (*Id.* ¶ 13) All three counts of the Complaint center on Abbott's allegedly inadequate warning and failure to warn of the risk of developing histoplasmosis when taking Humira. (*Id.* ¶ 12)

B. Histoplasmosis Is A Medically Well-Known And Labeled Risk Associated With Humira.

At the time Mr. Delano first received Humira treatment, the risk of opportunistic infections, in general, and histoplasmosis, in particular, were expressly disclosed in the FDA-approved Humira label. (*Id.* ¶¶ 14-18) The black box warning at the top of the warning label expressly warned of serious infections, including invasive fungal and other opportunistic infections, of which histoplasmosis is one:

> **WARNING: RISK OF SERIOUS INFECTIONS**
> **. . . invasive fungal infections, and other opportunistic infections, have been observed in patients receiving HUMIRA. Some of these infections have been fatal.**

(*Id.* ¶ 15) (emphasis in original) The later "Warnings and Precautions" section of the label contains similarly clear warnings about opportunistic infections and the risk of taking concomitant immunosuppressants, including histoplasmosis:

> **Serious infections**, sepsis, tuberculosis and **cases of opportunistic infections, including fatalities**, have been reported with the use of TNF blocking agents including HUMIRA. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their rheumatoid arthritis could predispose them to infections. In postmarketing experience, infections have been observed with various pathogens including viral, bacterial, fungal and protozoal organisms. Infections have been noted in all organ systems and have been reported in patients receiving HUMIRA alone or in combination with immunosuppressive agents. . . . Administration of HUMIRA should be discontinued if a patient develops a serious infection. Physicians should exercise caution when considering the use of HUMIRA in patients with a history of recurrent infection or underlying conditions which may predispose them to infections, or patients who have resided in regions where tuberculosis and **histoplasmosis** are endemic.

(*Id.* ¶ 16) (emphasis added) The "Adverse Reactions" section contains yet further warnings specifically mentioning histoplasmosis. The section lists "THE MOST SERIOUS ADVERSE REACTIONS" which included "SERIOUS INFECTIONS." (*Id.* ¶ 17) (emphasis in original) Going even further, Abbott included in the patient insert portion of the label, meant to be given directly to the patient, express warnings of infections, generally, and histoplasmosis, specifically:

> **What is the most important information I should know about HUMIRA?**
> HUMIRA is a medicine that affects your immune system. HUMIRA can lower the ability of your immune system to fight infections. **Serious infections have happened in patients receiving HUMIRA. These infections include TB (tuberculosis) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.**

> **HUMIRA may not be right for you. Before starting HUMIRA, tell your doctor if you:**
> - think you have any kind of infection, even if it is very minor (such as an open sore).
> - are being treated for an infection
> - have signs of an infection, such as a fever, cough, or flu-like symptoms
> - have lived in an area where TB or **histoplasmosis** is common. If you do not know if you have lived in an area where TB or **histoplasmosis** is common, ask your doctor.

(*Id.* ¶ 18) (emphasis added)

Months before Mr. Delano's February 2009 histoplasmosis diagnosis, the FDA had already issued a widely-publicized press release regarding the risk of histoplasmosis associated with Humira (and other TNF-inhibitors). (*Id.* ¶ 19) This September 4, 2008 FDA News Release included the following statements:

> Since the initial approval of the four TNF blockers, the prescribing information for these drugs has included information about the risk of serious infections, including fungal infections. However, based on reports reviewed by FDA, health care professionals are not consistently recognizing cases of ***histoplasmosis*** and other invasive fungal infections, leading to delays in treatment.
>
> ***Patients taking TNF blockers*** should be aware that they are ***more susceptible to serious fungal infections***. Those who develop a persistent fever, cough, shortness of breath, and fatigue should promptly seek medical attention. To assist in the diagnosis, ***those being treated with TNF blockers should tell their health care professionals where they live and what areas they have recently visited***. Patients who develop a fungal infection may be advised to stop the TNF blocker until they recover.
>
> FDA has reviewed 240 reports of ***histoplasmosis***, an infection caused by the fungus Histoplasma capsulatum, in patients being treated with Enbrel, ***Humira***, or Remicade. The majority of the reports involved people in the Ohio River and ***Mississippi River valleys*** (the fungus is commonly found in those areas). In at least 21 of the reports, ***histoplasmosis*** was initially not recognized by health care professionals, and antifungal treatment was delayed.

(*Id.* ¶ 20) (emphasis added)

Following the FDA action, in December 2008—months *before* Mr. Delano became ill and told medical personnel that he suspected Humira—the Humira label was further strengthened with regard to histoplasmosis in response to a request by the FDA. (*Id.* ¶¶ 21-25) This revised label and the FDA news release were available to Mr. Delano and his physicians in February 2009 when he was diagnosed with histoplasmosis and, as discussed below, Humira was identified by both Mr. Delano and physicians as the suspected cause. (*Id.* ¶¶ 19-31) The December 2008 label contained a black box warning on the front page that discussed serious infections, invasive fungal infections including histoplasmosis specifically, and use of Humira with other TNF blockers or immunosuppressants:

> WARNING: RISK OF SERIOUS INFECTIONS
>
> Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. HUMIRA should be discontinued if a patient develops a serious infection or sepsis.
>
> Reported infections include:
> • **Invasive fungal infections, including histoplasmosis**, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. **Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease.** Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.

(*Id.* ¶ 24) (emphasis added) "The Warnings and Precautions" section of the December 2008 label repeats these warnings, discussing histoplasmosis specifically, and is largely similar to the label that was already in place before Mr. Delano ever took Humira. (*Id.* ¶ 25)

C. By February 2009, Plaintiff And His Physicians Had Reason To Know His Condition May Be Related To Humira.

In February of 2009, as Mr. Delano sought treatment for his illness, he repeatedly told nurses and doctors that he believed Humira was the cause of his condition. (*Id.* ¶¶ 26-31) His healthcare providers similarly raised questions regarding the potential role Humira may have played in Mr. Delano's condition. (*Id.*) The following excerpts from Mr. Delano's medical records are illustrative:

- **February 2, 2009** Nurse's phone record: Mr. Delano "[s]topped his humira recently as ***he thought it*** wasn't working and ***possibly making him worse.***" (*Id.* ¶ 26) (emphasis added)
- **February 2, 2009** Medical record: Mr. Delano "states has been feeling dizzy and unsure of himself. States is having difficulty sleeping, diarrhea, headaches and nausea and poor appetite. States ***thinks*** (sic) ***is reaction to his medication Humira***." (*Id.* ¶ 27) (emphasis added)
- **February 5, 2009** Progress Notes: Mr. Delano had an "***[i]mmunocompromised status secondary to methotrexate/ humera*** (sic) rx" and that "Fungal cultures Pending." "Arthritis--hold methotrexate and humera (sic) until infectious process resolved." (*Id.* ¶ 28)
- **February 8, 2009** Discharge instructions "***[s]top taking*** the following: methotrexate and ***adalimumab [Humira]***. . ." (*Id.* ¶ 29)
- **February 25, 2009** Physician note: "Pt. here today with wife states he is to take sporonox now for next 6 months. ***States this illness occurred after he started taking humara*** (sic) for his psoriatic arthritis last fall." (*Id.* ¶ 30) (emphasis added)

D. Plaintiff's Complaint Was Barred by the Statute of Limitations Before Plaintiff Requested a Tolling Agreement.

Plaintiffs claim their lawsuit is timely because, "[p]ursuant to an agreement between the parties, the statute of limitations was tolled." (*Id.* ¶ 32) Plaintiffs offer no specifics regarding the timing of this agreement, nor could they. (*Id.* ¶ 33) The undisputed material facts show that any such agreement was not entered into until ***November 2010*** — over one and one-half years after Mr. Delano had repeatedly voiced his notice that Humira was potentially related to his histoplasmosis, and over two years following the widely-publicized September 2008 FDA press release regarding Humira and histoplasmosis. (*Id.* ¶¶ 19-21, 26-31, 34-36)

Indeed, the first communication regarding the *Delano* claims between Plaintiffs' and defense counsel did not occur until May 2010 (already more than one year after plaintiffs' clear notice of a potential claim). (*Id.* ¶ 34) There was no communication at that point of a tolling agreement. (*Id.* ¶ 35) And defense counsel have not located any reference to any tolling agreement regarding this claim until November 2010. (*Id.* ¶¶ 35-36) The November 2010 tolling agreement did not revive any existing claims (like those at issue here), which had already expired before the tolling agreement was reached.

LEGAL STANDARDS

Summary judgment is appropriate where a defendant shows "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. Proc. 56(a). "Accordingly, '[e]ntry of summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."'" *Whitfield v. Tennessee*, 639 F.3d 253, 258 (6th Cir. 2011) (quoting *Williams v. Stark Cnty. Bd. of Cnty. Comm'rs,* 7 Fed.Appx. 441, 445 (6th Cir. 2001) and *Celotex Corp. v. Catrett,* 477 U.S. 317, 322, 106 S.Ct. 2548, 2552 (1986)). Rule 56(b) specifies that "[u]nless a different time is set by local rule or the court orders otherwise, *a party may file a motion for summary judgment at any time. . . .*" Fed. R. Civ. Proc. 56(b) (emphasis added). The Advisory Committee Notes to the 2009 Amendments to Rule 56 state that Rule 56 was revised at that time to make clear that the Rule "allows a party to move for summary judgment at any time, even as early as the commencement of the action."[1] Advisory Comm. Notes, 2009 Amendment, Fed. R. Civ. Proc. 56.

ARGUMENT

I. Plaintiff's Claims Are Barred By Tennessee's One-Year Statute of Limitations.

The Tennessee Code provides for a one year statute of limitations for product liability actions. Tenn. Code Ann. § 28-3-104(b) ("[I]n products liability cases, the cause of action for injury to the person shall accrue on the date of the personal injury."); Tenn. Code Ann. § 29-28-103 ("Any action against a manufacturer or seller of a product for injury to person or property caused by its defective or unreasonably dangerous condition must be brought within the period fixed by § 28-3-104. . ."). Plaintiffs' claims are barred by this statute of limitations, and summary judgment must be granted for Abbott. In February 2009, Mr. Delano knew of his injury and believed Humira was its cause. (Statement of Undisputed Facts, ¶¶ 26-31) That same month, he was diagnosed with histoplasmosis – a potential side effect that was expressly discussed in Abbott's warning label. (*Id.* ¶¶ 8, 14-18, 24-25) Only after the limitations had run did Plaintiffs' counsel notify Abbott of the Delanos' claims and request a tolling agreement. (*Id.* ¶¶ 34-36)

"The statute of limitations commences to run when the plaintiff knows or has reason to know of the injury which is the basis of his action." *Sevier v. Turner,* 742 F.2d 262, 273 (6th Cir. 1984); *Roe v. Jefferson*, 875 S.W.2d 653, 657 (Tenn. 1994) (the statute is triggered when the plaintiff becomes "aware of facts sufficient to put a reasonable person on notice that he has

[1] The Advisory Committee Notes to the 2010 amendments further clarify that "[a]lthough the rule allows a motion for summary judgment to be filed at the commencement of the action, in many cases the motion will be premature until the nonmovant has had time to file a responsive pleading or other proceedings have been had. Scheduling orders or other pretrial orders can regulate timing to fit the needs of the case." Advisory Cmte Notes, 2010 Amendment, Fed. R. Civ. Proc. 56. There is no scheduling order here that restricts Abbott from filing the instant motion.

suffered an injury as a result of wrongful conduct"). "A plaintiff has reason to know of his injury when he should have discovered it through the exercise of reasonable diligence." *Ball v. Union Carbide Corp.*, 385 F.3d 713, 721 (6th Cir. 2004) (quoting *Sevier,* 742 F.2d at 273) (affirming district court's grant of summary judgment on statute of limitations grounds against plaintiffs who alleged that defendant caused their cancer). In a case such as this involving the development of a medical condition, "[w]hen the injury is contracting [disease], the claim will accrue when the plaintiff knew or should have known of the disease . . . In that event, a plaintiff must clearly plead that the injury occurred within the statute of limitations period." *Id.* at 723.

In the Delanos' case, their cause of action accrued at the latest when Mr. Delano was diagnosed with histoplasmosis on February 19, 2009. *See id.* Moreover, Mr. Delano by that time already believed that Humira caused his illness, further confirming that Plaintiffs' cause of action accrued at the latest in February 2009. *See id.* at 721. Mr. Delano's medical records repeatedly show that in February 2009 he told several of his treating or consulting medical providers that he believed Humira was the cause of his illness. (*Id.* ¶¶ 26-31) This settles the question of whether the Delanos were alerted that they had a possible cause of action. *See Mich. United Food & Commercial Workers Unions & Drug & Mercantile Employees Joint Health & Welfare Fund v. Muir Co.,* 992 F.2d 594, 600 (6th Cir. 1993) ("In defining the concept of due diligence, the 6th Cir. has 'looked to what event should have alerted the typical lay person to protect his or her rights.' ") (quoting *Dixon v. Anderson,* 928 F.2d 212, 215 (6th Cir. 1991)); *Jastrebski v. Smith & Nephew Richards, Inc.*, Case No. 02A01–9803–CV–00068, 1999 WL 144935, at *3 (Tenn. Ct. App. Mar. 18, 1999) (finding the statute of limitations to begin when plaintiff should have discovered a product caused his injuries).

Once Mr. Delano concluded that Humira may have caused his illness and that illness was diagnosed as histoplasmosis, the Delanos knew all that was necessary for the statute of limitations to begin running. "[T]he plaintiff [need not] actually know that the injury constitutes a breach of the appropriate legal standard" for the statute of limitations to begin to run. *Jastrebski*, 1999 WL 144935, at *4 (quoting *Roe*, 875 S.W.2d at 657). The statute of limitations "is tolled only during the period when the plaintiff has no knowledge at all that a wrong has occurred, and, as a reasonable person, is not put on inquiry." *Id.* at *3-4. (citing *Teeters v. Currey,* 518 S.W.2d 512 (Tenn. 1974) (Harbison, concurring)). Because there is no dispute that Mr. Delano suspected that Humira was the alleged cause of his injury, he was put on inquiry and notice on February 19, 2009 of his cause of action and was obligated to timely file suit. *See, e.g., Hicks v. Hines, Inc.,* 826 F.2d 1543, 1544 (6th Cir. 1987) (explaining that the "discovery rule" tolls "the running of the statute of limitations to the date by which the plaintiff reasonably should have discovered both cause and injury." (citing *U.S. v. Kubrick*, 444 U.S. 111, 122 (1979))*; Doe v. Catholic Bishop for Diocese of Memphis*, 306 S.W.3d 712, 718 (Tenn. Ct. App. 2008) ("the cause of action accrues and the statute of limitations begins to run when the injury occurs or is discovered, or when *in the exercise of reasonable care and diligence, it should have been discovered*.") (emphasis added) (citing *Potts v. Celotex Corp.,* 796 S.W.2d 678, 680 (Tenn. 1990)). Given the suspicion he expressed to his medical providers, if Mr. Delano had exercised even a minimal amount of diligence, he would have seen the that the warning label was changed between the time he first took Humira and the time he became ill, with the new label containing the very black box warnings that Plaintiffs *now* allege should have been in effect when he was prescribed the drug. Such failure to exercise such minimal diligence using basic, publicly available, FDA-approved material is fatal to Plaintiffs' claims.

When Mr. Delano believed Humira was the alleged cause of his histoplasmosis, he had available to him all of the information upon which he bases his claims. (Statement of Undisputed Facts, ¶¶ 14-19, 21-22, 24-25) The Complaint alleges that the Delanos were not adequately warned in 2008 about the risk of developing histoplasmosis when taking Humira. (*Id.* ¶¶ 11-12) Plaintiffs allege that Abbott should have warned the Delanos and/or their doctors in September and October 2008, when Mr. Delano was prescribed and began taking Humira, using the warnings requested by the FDA in its letter of September 4, 2008. (*Id.*) But there is no dispute that Abbott did implement the FDA's requested label changes on December 22, 2008. (*Id.* ¶¶ 19-20, 23-25) If in fact Mr. Delano did not believe he had been warned adequately, as the Complaint alleges, once he was diagnosed with histoplasmosis and suspected that Humira might be a cause, Mr. Delano was on adequate notice of his claim. *See Hicks*, 826 F.2d at 1544; *Austein v. Riverwood Int'l USA, Inc.*, Case No. 02S01-9507-CH-00059, 1996 WL 79362, at *3 (Tenn. Feb. 23, 1996) (remanding products liability action for determination of whether plaintiff acted with due diligence in discovering that his injury was related to defendant). All he needed to do to investigate his cause of action was to read the two Humira warning labels—the one in effect when he began his Humira treatment and the one Abbott revised at the FDA's request and began using almost two months *before* Mr. Delano was diagnosed with histoplasmosis. Plaintiffs allege that the label in effect at the time Mr. Delano took Humira did not contain the particular warnings the FDA requested in its September 4, 2008 letter, but it is indisputable that those particular warnings *were* included in the Humira label available to Mr. Delano when he was diagnosed with histoplasmosis and suspected Humira was its cause. (*Id.* ¶¶ 14-18, 23-25) Given Mr. Delano's suspicion that Humira had caused his illness, had he made an effort to review Abbott's label, he would have seen the very warnings that plaintiffs now allege were required in order to put someone on notice of the risks associated with the drug.

In sum, by February 2009 Mr. Delano "is deemed to have discovered the right of action [because] he [was] aware of facts sufficient to put a reasonable person on notice that he suffered an injury as a result of wrongful conduct." *Jastrebski*, 1999 WL 144935, at *4 (quoting *Roe*, 875 S.W.2d at 657). The Delanos nevertheless failed to bring their cause of action or seek a tolling agreement with Abbott within one year. The complaint is untimely, and summary judgment must be granted.

II. The One-Year Statute Of Limitations Requires Summary Judgment On All Of Plaintiffs' Claims.

Although Plaintiffs include in their Complaint a count alleging breach of warranty, it is based on the same premise as the other counts—failure to warn—and is therefore subject to the one-year statute of limitations. The gravamen of Plaintiffs' complaint is one of personal injuries, not breach of warranty, thus the one year statute of limitations for personal injury applies. "It is well-settled law in this state that 'the gravamen of an action, rather than its designation as an action for tort or contract, determines the applicable statute of limitations.'" *Liggett v. Brentwood Builders, LLC*, Case No. M2007-00444-COA-R3-CV, 2008 WL 836115, at *3 (Tenn. Ct. App. March 27, 2008) (quoting *Pera v. Kroger Co.,* 674 S.W.2d 715, 719 (Tenn. 1984 and citing *Whaley v. Perkins,* 197 S.W.3d 665, 670 (Tenn. 2006)).

To determine the gravamen of a complaint, a court will look to the "subject matter of the controversy and not to the remedial procedure. *Id.* (citing *Kirby Farms Homeowners Ass'n v. Citicorp, Citibank, N.A.,* 773 S.W.2d 249, 251 (Tenn. Ct. App. 1989)). The Delanos assert that Abbott breached its "warranty obligations under Tennessee law" and that "Plaintiffs had the right to expect Abbott to stand behind its product and to bear the burden for any injuries Fred Delano sustained as a result of his use of its product." (Cmplt., ¶ 86). Yet there are no allegations within Plaintiffs' Complaint which support a breach of express or implied warranty claim other than those alleging that Abbott failed to warn adequately of the risk posed by Humira use.

Tennessee's statute regarding implied warranties provides that in order for goods to be merchantable, they must:

(a) "pass without objection in the trade under the contract description; and

(b) in the case of fungible goods, are of fair average quality within the description; and

(c) are fit for the ordinary purposes for which such goods are used; and

(d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and

(e) are adequately contained, packaged, and labeled as the agreement may require; and

(f) conform to the promises or affirmations of fact made on the container or label if any."

Tenn. Code Ann. § 47-2-314(2). Because Plaintiffs' Complaint does not offer a single factual allegation which demonstrates the breach of the warranty requirements set forth in Tenn. Code Ann. § 47-2-314, the gravamen of their Complaint is personal injury and the one year statute of limitations for such causes of action applies.

CONCLUSION

For the foregoing reasons, Defendant Abbott Laboratories respectfully requests that this Court grant summary judgment for Abbott on all of Plaintiffs' Counts.

Dated: September 6, 2011

Respectfully submitted,

s/Emily Turner Landry

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANT ABBOTT LABORATORIES' MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT was filed electronically on this 6th day of September 2011, and will, therefore, be served electronically upon:

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